In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS No. 21-0854V

VIRGINIA MCGEE,

Petitioner,

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SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: December 5, 2024

Ronald Craig Homer, Conway, Homer, P.C., Boston, MA, for Petitioner.

Dorian Hurley, U.S. Department of Justice, Washington, DC, for Respondent.

FACT RULING AND ORDER <u>DENYING RESPONDENT'S MOTION TO DISMISS</u>¹

On February 3, 2021, Virginia McGee filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the "Vaccine Act"). Petitioner alleged that she suffered a right shoulder injury related to vaccine administration ("SIRVA") as a result of an influenza ("flu") vaccine received on August 26, 2020.³ Amended Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters.

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¹ Because this Ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the Ruling will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2018).

³ Petitioner filed an Amended Petition on June 22, 2022, alleging that she received the flu vaccine in her right deltoid on August 26, 2020, instead of August 28, 2020, as the original petition alleged.

Although Respondent has moved to dismiss the claim, I find that the record evidence preponderantly establishes that Petitioner suffered the residual effects of her injury for more than six months. I also find that Petitioner has shown by preponderant evidence that her right shoulder pain began within 48 hours of vaccination as required to satisfy a Table SIRVA claim.

I. Relevant Procedural History

The case was activated on August 16, 2022 (ECF No. 31). On September 11, 2023, Respondent filed his Rule 4(c) Report combined with a Motion to Dismiss (ECF No. 42). Respondent maintains that the medical records do not demonstrate that Petitioner experienced the residual effects of her SIRVA for more than six months, and thus she did not meet the statutory severity requirement. *Id.* at 1. In addition, Respondent states that Petitioner cannot preponderantly prove that her right shoulder pain began within 48 hours of vaccination, and thus, her Table SIRVA claim must fail. *Id.* at 16. Finally, Respondent states that Petitioner cannot establish that her injury was caused-in-fact by the flu vaccine. *Id.* at 15.

Petitioner filed a Response to the Rule 4(c) Report and Motion to Dismiss on February 1, 2024. ECF No. 45. Respondent did not file a Reply. Thus, Respondent's Motion to Dismiss is now ripe for resolution.

II. Legal Standards

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1), including the factual circumstances surrounding the claim. Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. Section 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id.*

To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. See Burns v. Sec'y of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." Cucuras v. Sec'y of Health & Human Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

To overcome the presumptive accuracy of medical records testimony, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." *Sanchez v. Sec'y of Health & Human Servs.*, No. 11–685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). The Federal Circuit has "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Human Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021) (explaining that a patient may not report every ailment, or a physician may enter information incorrectly or not record everything he or she observes).

1. Severity Requirement

In addition to requirements concerning the vaccination received and the lack of other award or settlement, a petitioner must establish that he or she suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination he or she received. Section 11(c)(1)(C). The Vaccine Act further includes a "severity requirement," pursuant to which a petitioner demonstrate that they:

(i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine, or (ii) died from the administration of the vaccine, or (iii) suffered such illness, disability, injury or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention.

Section 11(c)(1)(D).

"[T]he fact that a petitioner has been discharged from medical care does not necessarily indicate that there are no remaining or residual effects from her alleged injury." *Morine v. Sec'y of Health & Human Servs.*, No. 17-1013, 2019 WL 978825, at *4 (Fed. CI. Spec. Mstr. Jan. 23, 2019); see also Herren v. Sec'y of Health & Human Servs., No. 13-1000V, 2014 WL 3889070, at *3 (Fed. CI. Spec. Mstr. July 18, 2014) ("a discharge from medical care does not necessarily indicate there are no residual effects"). "A treatment gap . . . does not automatically mean severity cannot be established." *Law v. Sec'y of Health & Human Servs.*, No. 21-0699V, 2023 WL 2641502, at *5 (Fed. CI. Spec. Mstr. Feb. 23, 2023) (finding severity requirement met where petitioner sought care for under three months and had met physical therapy goals but still lacked full range of motion and experienced difficulty with certain activities, then returned to care nearly five months later reporting stiffness and continuing restrictions in motion); *see also Peeples v. Sec'y of Health & Human Servs.*, No. 20-0634V, 2022 WL 2387749 (Fed. CI. Spec. Mstr. May

26, 2022) (finding severity requirement met where the petitioner sought care for four months, followed by fifteen-month gap); *Silvestri v. Sec'y of Health & Human Servs.*, No. 19-1045V, 2021 WL 4205313 (Fed. Cl. Spec. Mstr. Aug. 16, 2021) (finding severity requirement satisfied where petitioner did not seek additional treatment after the fivementh mark.

2. SIRVA QAI Requirements

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of a flu vaccine. 42 C.F. R. § 100.3(a)(XIV)(B). The criteria establishing a SIRVA under the accompanying Qualifications and Aids to Interpretation ("QAI") are as follows:

Shoulder injury related to vaccine administration (SIRVA). SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

- (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
- (ii) Pain occurs within the specified time frame;
- (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and

(iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

III. Relevant Factual History

This ruling contains only a brief overview of the facts most relevant to the parties' dispute. A full recitation of the facts can be found in the Petition, Amended Petition, Respondent's Rule 4(c) Report and Motion to Dismiss, and in Petitioner's Response to the Motion to Dismiss.

A. Medical Records

On August 26, 2020, Ms. McGee (then 65-years-old) received a flu vaccine intramuscularly in her right deltoid at CVS Pharmacy located in Sarasota, Florida. Ex. 1 at 4-6. Her medical history includes notations for osteopenia and shoulder tendinitis. Ex. 2 at 8; Ex. 9 at 18, 25; Ex. 10 at 1, 5, 8. In her declaration, Ms. McGee stated that,

[t]he shot was injected at the very top of my right shoulder, too high. I felt this was not right. The next day, I had inflammation and soreness in the shoulder at the injection site. The following days, into the week, the shoulder pain got worse, and I had very limited range of motion. My biggest problem was sleeping, and I had to immediately stop all my physical activities. The pain was not getting better, so I made an appointment to see my general practitioner on September 15, 2020.

Ex. 14 at 2.

Twenty (20) days later, on September 15, 2020, Ms. McGee had a telehealth visit with Linda Martell, Advanced Registered Nurse Practitioner ("ARNP"), reporting right shoulder pain for the past two weeks. Ex. 9 at 13-16. Ms. McGee reported that she had

right shoulder pain with range of motion since getting her flu vaccine in that shoulder.⁴ Id. at 13. She maintained that the site pain resolved within a couple of days, but the shoulder pain remained. Id. at 15. Ms. McGee also reported that her pain was at an 8 to 9/10 when she lifted her right arm above her head. Id. She was diagnosed with pain of the right shoulder joint and was prescribed 10mg of Prednisone and a 21 pill Dosepak. Id. Ms. McGee was instructed to return if her symptoms did not significantly improve. Id.

Ms. McGee returned to ARNP Martell on September 22, 2020. Ex. 9 at 9-10. She reported that the Prednisone had been very effective, but her pain had gradually returned since finishing the prescription. Id. at 11. An exam revealed limited range of motion ("ROM") and tenderness to the deltoid region. Id. at 12. An x-ray of the right shoulder revealed moderate acromioclavicular ("AC") joint degeneration and osteopenia. Ex. 10 at 18. ARNP Martell noted that the cause of Ms. McGee's discomfort was "likely early arthritis," but that "other differentials could be rotator cuff disorder secondary to repetitive motion i.e., golfing, tendonitis, [or an] adverse effect from [her] flu shot." Ex. 9 at 12. She provided Ms. McGee with orthopedic and physical therapy ("PT") referrals and prescribed 800 mg ibuprofen. Ex. 6 at 21; Ex. 9 at 12; Ex. 11 at 60.

On September 24, 2020, Ms. McGee underwent an initial evaluation and PT session at Venice Regional Bayfront Health Physical Therapy and Rehab Center ("VRBH"). Ex. 11 at 64-68. She reported that her right shoulder pain started three to four weeks prior, had progressively gotten worse, and increased with movement. Id. at 64. Ms. McGee stated that her ROM was limited and that she normally golfed three times a week but had stopped golfing due to her right shoulder pain. Id. She rated her pain as a 5/10. *Id.* at 65. Petitioner was tender upon palpation to the right deltoid anteriorly and treated with gentle passive stretching on her right shoulder and provided with a home exercise program. Id. at 67-68.

On October 9, 2020, Ms. McGee was examined by orthopedic surgeon Julio Gonzalez, M.D., J.D., at the Orthopaedic Center of Venice for her right shoulder pain. Ex. 6 at 13-16. After an exam and review of her prior x-ray, Dr. Gonzalez noted that Petitioner had "[a]rthralgia of [the] right shoulder region" and administered a corticosteroid injection into her right AC joint. *Id.* at 15-16.

Ms. McGee returned to VRBH for PT five additional times between September 28 and October 7, 2020. Ex. 11 at 54-59, 83-86; Ex. 13 at 19-22. At her October 7, 2020 PT

⁴ There is a notation by ARNP Martell in these notes that Petitioner had "a history of tendinitis in that shoulder however she states she has not had that for greater than 5 years." Ex. 9 at 15. In her June 7, 2022 declaration, Ms. McGee asserted that she had reviewed nurse Martell's notes, and that she "disagree[d] with this notation." Ex. 14 at ¶ 2. Petitioner further asserted that she has "never had issues with [her] right shoulder prior to [her] August 26, 2020 flu vaccine." Id.

session, Ms. McGee reported that she was feeling better since starting PT and rated her a pain as a zero on a ten-point scale. Ex. 13 at 22.

Ms. McGee returned to Dr. Gonzalez on October 30, 2020. Ex. 6 at 17-18. She reported that her right shoulder pain and improved since receiving the injection and starting physical therapy. *Id.* Ms. McGee also reported that she was "able to perform all the activities she desires...", although she still had some pain with elevation and some activities. *Id.* Dr. Gonzalez recommended that she continue with her activities as tolerated and instructed her to continue with her rotator cuff strengthening exercises. *Id.*

Ms. McGee continued with physical therapy through January 5, 2021, attending a total of 15 sessions. Ex. 11 at 12-26. At her last session, four and a half months post-vaccination, she reported no shoulder pain and stated that she felt comfortable being discharged at that time to a home exercise program. *Id.* at 21. Her physical therapist noted that her goals had been partially met and provided her with a home exercise program. *Id.* It was noted that Ms. McGee still had some reduced range of motion at the time. *Id.* at 23. In her declaration, Ms. McGee stated,

I was discharged from PT in January 2021 and started back with golf and other activities. However, I was not able to perform any of them at the level I could before because of my continued pain. I improved but was not one hundred percent. Into the spring and summer of 2021, I was reminded daily that my right shoulder remained limited. I experienced pain when I swung a golf club, which limited me in the game I truly enjoyed. I had pain in my shoulder when trying to put a book or dish on a high shelf or reach behind for something on the back seat of the car. Some things I could not do at all, like the simple task of pulling a sweater or shirt off overhead.

I am a firm believer in exercise and when I was given the home exercise program to perform at the conclusion of my in-person physical therapy, I dedicated myself to the exercises to keep my right shoulder from regressing. I incorporated the exercises I was given by my physical therapist into my exercise routine. I found them very helpful as I could not do the heavy weight exercises I was accustomed to prior to my shoulder injury. I found the best exercises involved the resistance bands and the second best the rowing machine.

Ex. 14 at 3-4.

On July 15, 2021 (now approximately six months after her last PT session), Ms. McGee visited primary care physician ("PCP") Alka Nair, M.D., at GCMG for a Medicare wellness visit. Ex. 12 at 8-16. A musculoskeletal exam revealed normal movement of all extremities. *Id.* at 7. In Dr. Nair's discussion notes, she noted "shoulder pain – stable" and noted that Ms. McGee had seen Dr. Gonzalez and "had a shot [and would] get [s]hots periodically." *Id.* at 10. Petitioner reported that she was playing golf and pickleball regularly. *Id.* at 11.

Ms. McGee continued to visit various health care providers through end of 2021, and into the first half of 2022, but she did not complain about or receive treatment for her shoulder at any of these visits, although she stated in her declaration that she continued to experience right shoulder pain. *See, e.g.*, Ex. 19 at 19-61 (eight dermatology visits between August 18, 2021, and March 11, 2022); Ex. 21 at 24 (February 8, 2022 gynecology appointment); Ex. 20 at 3 (March 31, 2022 eye exam); Ex. 14 at 4-5 (declaration).

On July 15, 2022, more than 18 months after her last PT session for her shoulder and more than one year since her last Medicare wellness visit, Ms. McGee returned to Dr. Nair for another annual Medicare wellness visit. Ex. 17 at 8-17. Petitioner reported that her right shoulder pain was "acting up again" depending on the activity. *Id.* at 10. A physical exam revealed normal strength and ROM in all extremities. *Id.* at 15. Dr. Nair assessed Ms. McGee as having pain of her right shoulder joint and noted underneath that assessment: "unstable - not as bad as previously," although Ms. McGee reported her current pain level at 5/10 *Id.* at 16. Dr. Nair referred Petitioner to an orthopedic surgeon for a cortisone injection. *Id.*

On July 28, 2022, Ms. McGee visited a new provider, orthopedic surgeon Christopher Sforzo, M.D., at Stewart Orthopedics, for evaluation of her right shoulder symptoms. Ex. 18 at 7-9. She reported that she had received a flu vaccine in August 2020, "felt increased pain," and had been provided a prednisone taper by her PCP that had had provided temporary relief. *Id.* at 7. Ms. McGee also reported that she had received a cortisone injection and PT that had "provided relief until recently." *Id.* On physical exam, Petitioner's ROM in both shoulders was "grossly intact," but she had pain in her right shoulder with external rotation to 85 degrees and empty can test and Hawkin's impingement test were both positive. *Id.* at 7-8. An ultrasound of her right shoulder revealed increased fluid in the right biceps tendon and subacromial space, and moderate bursitis and tendinopathy, but no rotator cuff tears. *Id.* at 8. An x-ray revealed severe AC joint osteoarthritis. *Id.* Dr. Sforzo diagnosed Ms. McGee with subacromial bursitis of the right shoulder and counseled her that her x-rays showed severe AC joint osteoarthritis. *Id.* Petitioner received a steroid injection in the subacromial bursal space. *Id.*

Ms. McGee continued to visit various health care providers through the end of 2022, but she did not complain about or receive treatment for her right shoulder at any of these visits. *See, e.g.*, Ex. 22 at 21 (September 9, 2022 urgent care visit for sinus infection); Ex. 19 at 12 (September 15, 2022 dermatology visit); Ex. 21 at 18 (November 16, 2022 mammogram); Ex. 22 at 16-17 (November 16, 2022 screening for osteoporosis that revealed osteopenia).

No medical records after November 2022 have been filed.

B. Declarations

Ms. McGee filed two declarations and a declaration from her husband in support of her claim. Exs. 14-16. In her declaration, Ms. McGee explained that prior to vaccination, she was very active and healthy. Ex. 14 at 1. She stated that her weekly routine consisted of golf three days a week, an intense cardio workout with a trainer three days a week, pickleball twice a week and brisk walks through her golf community. *Id.* Ms. McGee stated that she rarely needed to visit doctors other than for her annual wellness visits, mammograms, and dermatology visits. *Id.* She explained that from the date of vaccination in August 2020 through the end of 2020, she was not able to engage in any of those physical activities. *Id.* While her pain improved over the next year, Ms. McGee stated that she was not 100% and would experience pain when reaching above or behind her. *Id.* at 4. Ms. McGee explained that she worked diligently at her home exercise program to improve her right shoulder pain and continues to perform those exercises to this day. *Id.* at 4-5. She states that her current level of pain is "something [she] can live with," but that her range of motion and strength remains limited. *Id.* at 5.

Petitioner's husband, Bill McGee, stated in his declaration that his wife could not play golf, which was the main activity in the community where they lived. Ex. 15 at 1-2. He explained that Petitioner continues to experience pain in her right shoulder and that she continues to perform her physical therapy exercises on her own. *Id.* at 4.

IV. The Parties' Arguments

Respondent argues that Petitioner has not demonstrated by preponderant evidence that she experienced residual effects of her SIRVA for more than six months. Respondent's Rule 4(c) Report and Motion to Dismiss, filed September 11, 2023, at 7 (ECF No. 42) ("Mot."). Respondent acknowledges that Petitioner sought care several times in the first four and a half months after vaccination, but notes that this was followed by an 18-month gap in treatment (between January 2021 and July 2022). Mot. at 9. At her July 15, 2022 appointment, which was an annual wellness exam, Ms. McGee reported that her shoulder was "acting up again," but was "not bad as previously." Ex. 17 at 10, 16.

Respondent also argues that when Ms. McGee visited Dr. Sforzo on July 28, 2022, she reported that the steroid injection had provided relief "until recently." Ex. 18 at 7. This, to Respondent, is proof that Ms. McGee's initial shoulder pain post vaccination had "resolved within six months." Opp. at 9.

Respondent also argues that although Ms. McGee contends that she was still experiencing shoulder pain after being discharged from PT in January 2021, her claims are not corroborated by the medical records. Opp. at 10. Respondent argues that Petitioner's declaration and the declaration of her husband were prepared almost two years after vaccination and for purposes of litigation and are not adequate to overcome the reliability of the medical records which do not support the contention that Petitioner suffered a shoulder injury for more than six months. *Id*.

Respondent also maintains that Ms. McGee has never explained why she did not seek treatment for her right shoulder during the 18-month gap in treatment from January 5, 2021, to July 15, 2022. Mot. at 12. In addition, Respondent notes that Petitioner was playing golf and pickleball regularly and had established "a pattern of seeking medical care and following up with medical providers when she needed care." *Id.* Respondent argues that Ms. McGee has not established that the symptoms she experienced in July 2022 were related to the pain she experienced in her shoulder immediately following vaccination, 18 months earlier. Mot. at 12.

Petitioner maintains in response that her symptoms continued for longer than six months, satisfying the statutory severity requirement. Opp. at 13. She explains that when she was discharged from physical therapy four and a half months after vaccination, her SIRVA had improved but had not resolved as evidenced by her discharge paperwork. *Id.* at 12. Petitioner also explained that during the 18-month period when she did not seek formal treatment, she "dedicate herself to her home exercise program to maintain the improvement she gained while in physical therapy. *Id.* at 14. Petitioner explained that 18 months after she was discharged from physical therapy, the medical records prove that she continued to experience right shoulder deficits that had improved but not resolved. *Id.* at 15.

Petitioner also contends that the intervening medical appointments she had during that 18-month gap were for specialist visits where she would not have been expected to discuss the ongoing residual effects of her SIRVA, such as dermatology, ophthalmology, and mammogram visits. Opp. at 17.

Respondent has also argued that even if the six-month severity requirement is overcome, Petitioner has still failed to prove a Table SIRVA claim because she cannot prove that her right shoulder pain began within 48-hours of vaccination. Mot. at 15.

Petitioner maintains that her shoulder pain began immediately and within 48 hours of vaccination. Opp. at 27-28.

ANALYSIS

V. Statutory Severity Requirement

In order to demonstrate severity, Petitioner must show that she suffered residual effects through late February 2021. Having reviewed the medical records and other evidence, I find no evidence to support Respondent's argument that Petitioner's pause in care starting in January 2021 establishes that her shoulder pain had resolved by that time. On the contrary, the records show that Ms. McGee was still experiencing right shoulder deficits, including reduced range of motion, when she was discharged from physical therapy in January 2021 (four and half months post-vaccination), with a home exercise program. Petitioner also stated that she received some relief from a cortisone injection in October 2020, but that its effects extended through the time she initially ceased care.

The treatment gap at issue in this case is inordinately long for a SIRVA, and it includes instances in which Petitioner continued to seek medical care – allowing for the inference that she could have also obtained treatment for shoulder pain, had it continued. However, I credit Petitioner's argument that these medical appointments were for unrelated conditions where discussing the residual effects of a SIRVA injury was not necessarily warranted.

There is also some evidence that *weakly* supports the conclusion that Petitioner's SIRVA had not fully resolved by mid-2022. Thus, when Ms. McGee was evaluated in July 2022, she had pain with rotation in her right shoulder and the empty can and Hawkin's impingement tests were both positive. An ultrasound of her right shoulder also revealed increased fluid in the right biceps tendon and subacromial space, and moderate bursitis and tendinopathy, but no rotator cuff tears. While it is more difficult to attribute these concerns to a SIRVA that began in August 2020 (hence nearly *two years earlier*), these complaints are not wholly distinguishable either.

Thus, the evidence preponderantly supports a finding that Petitioner experienced residual effects of her injury for more than six months, satisfying the statutory severity requirement. (I do note, however, that the lengthy treatment gap will bear on damages in this case – and Petitioner must therefore take this fairly glaring deficiency in her claim into account).

VI. Onset

Regarding the onset of Petitioner's pain, in order to meet the definition of a Table SIRVA, a petitioner must show that she experienced the first symptom or onset within 48 hours of vaccination (42 C.F.R. § 100.3(a)(XIV)(B)) and that her pain occurred within that same 48-hour period (42 C.F.R. § 100.3(c)(10)(ii) (QAI criteria)).

Respondent's argument rests on the fact that Ms. McGee did not report her shoulder injury to a medical provider until 20 days after vaccination. Mot. at 15. And at that visit, Petitioner reported a two-week history of shoulder pain, which would place the onset of shoulder pain on September 1, 2020, six days post-vaccination. Id. Respondent also notes that while Petitioner referenced pain when receiving her flu vaccine at that visit, she distinguished her vaccine-related pain from her shoulder pain, "[o]nly relation [petitioner] can make is she did receive her flu vaccine in that shoulder at onset of pain[,] however[,] the vaccine site pain seemed to resolve within a couple of days[.] However[,] shoulder pain remains." Id. Respondent also notes that on September 24, 2020, at Petitioner's first PT visit for her right shoulder pain, she reported that her pain began three to four weeks prior, which would place onset between August 27 and September 3, 2020 (i.e., one day to eight days post-vaccination). Respondent suggests that these records suggest the onset of her symptoms may have been far outside of a 48-hour onset. Id. Thus, in light of the 20-day gap between vaccination and the first report of right shoulder pain, and the inconsistent and vague reporting of when onset of her shoulder pain began, Petitioner has not established the requirements of the QAI for a SIRVA Table injury.

This evidence, however, is undermined by other medical records that do place onset of Petitioner's right shoulder pain within 48 hours. For example, although the medical records from the September 15, 2020 visit do state that Petitioner experienced shoulder pain for the prior two weeks, more detailed information contained within that same note pinpoint the onset as occurring at the time of vaccination. The note states that, "[o]nly relation patient can make is she did receive her flu vaccine in that shoulder at onset of pain however the vaccine site pain seemed to resolve within a couple of days [h]owever shoulder pain remains." Ex. 9 at 15. The more detailed information regarding onset contained within this record is much more persuasive than the more general "2 weeks of right shoulder pain." In addition, on September 24, 2020, at Petitioner's initial physical therapy evaluation, she stated that her pain started approximately three to four weeks ago. Ex. 11 at 64. Four weeks prior to September 24, 2020, was August 27, 2020, which is one day after her flu vaccine on August 26, 2020. Thus, the evidence preponderates in Petitioner's favor that her shoulder pain began within 48-hours of her August 26, 2020 flu vaccination.

VII. Other Requirements for Entitlement

Even if a petitioner has satisfied the requirements of a Table injury or established causation-in-fact, he or she must also provide preponderant evidence of the additional requirements of Section 11(c), *i.e.*, receipt of a covered vaccine, etc. See generally Section 11(c)(1)(A)(B)(D)(E). But those remaining elements are established or undisputed. Petitioner has therefore established that she suffered a Table SIRVA, satisfying all other requirements for compensation.

VIII. Conclusion and Scheduling Order

Based on my review of the record as a whole, I find that the statutory severity requirement is satisfied by preponderant evidence. Therefore, Respondent's motion to dismiss is **DENIED**. I also find that Petitioner's right shoulder pain began within 48-hours of the August 26, 2020 flu vaccination. Therefore, Respondent shall file an Amended Rule 4(c) report adopting the findings in this Ruling by **Friday**, **January 17**, **2025**.

IT IS SO ORDERED.

<u>s/Brian H. Corcoran</u> Brian H. Corcoran Chief Special Master